

Sensorion and Cochlear to begin first clinical trial of SENS-401 for hearing preservation in combination with cochlear implantation

- *The study will aim to measure perilymph PK of SENS401 and to explore the therapeutic effect of SENS-401 on early hearing outcomes upon cochlear implantation*
- *The trial will be fully funded under the existing agreement between Cochlear and Sensorion*

Montpellier, France and Sydney, Australia, September 8, 2021 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders, and Cochlear Limited (ASX:COH), the global leader in implantable hearing solutions, announce the initiation of a pilot study of the first-in-class small molecule drug SENS-401 (Arazasetron) in patients scheduled for cochlear implantation.

The study will be sponsored by Sensorion and the proposed design is expected to be submitted to the regulatory authorities in the second half of 2021.

“We are excited Cochlear has decided to work with us to further develop SENS-401 in clinical studies” said **Nawal Ouzren, CEO of Sensorion**. “Our healthy volunteer studies and our ongoing phase 2 study in sudden sensorineural hearing loss (SSNHL) have already demonstrated the safety of SENS-401, and our observations in preclinical models of cochlear implantation have established first promising efficacy signals. This new exploratory study aims to provide further clinical validation for the broadening of our pipeline, alongside our promising gene therapies, and will provide us with information on the drug’s potential beneficial effect on hearing outcomes achieved with Cochlear’s implantable devices.”

The results of Sensorion’s *in vivo* preclinical studies on the use of SENS-401 in conjunction with cochlear transplantation were encouraging. In an established preclinical model, the combination of SENS-401 with cochlear implants preserved residual acoustic hearing at statistically significant levels at a frequency located beyond the electrode array, compared to placebo. In the preclinical study, drug or placebo was delivered via an eluting electrode. The new clinical study will explore the potential efficacy of SENS-401 in combination with cochlear implants.

“As the leader in the cochlear implant industry, we invest more than any other company in product innovation to optimise outcomes for those with hearing implants,” said **Jan Janssen, Chief Technology Officer, Cochlear**. “We believe the combination of cochlear implant technology and pharma therapies has the potential to enhance patient outcomes in terms of preservation of residual hearing and speech understanding. We recently announced the start of a pivotal clinical study with a dexamethasone-eluting cochlear implant electrode, which is a first in our industry. Through the collaboration with Sensorion in the SENS-401 study, we will gain further insights around potential combination therapies for people with severe to profound hearing loss.”

About SENS-401

SENS-401 (Arazasetron), is a drug candidate that aims to protect and preserve inner ear tissue from damage that can cause progressive or sequellar hearing impairment. A small molecule that can be taken orally or via an injection, SENS-401 has received Orphan Drug Designation in Europe for the treatment of sudden sensorineural hearing loss, and Orphan Drug Designation from the US FDA for the prevention of platinum-induced ototoxicity in pediatric population. It has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA).

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders. Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) for sudden sensorineural hearing loss (SSNHL). Sensorion has built a unique R&D technology platform

to expand its understanding of the pathophysiology and etiology of inner ear related diseases enabling it to select the best targets and modalities for drug candidates. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses. Sensorion has launched three gene therapy programs, currently at preclinical stage, aimed at correcting hereditary monogenic forms of deafness including deafness caused by a mutation of the gene encoding for Otoferlin, hearing loss related to gene target GJB2 as well as Usher Syndrome Type 1 to potentially address important hearing loss segments in adults and children. The Company is potentially uniquely placed, through its platforms and pipeline of potential therapeutics, to make a lasting positive impact on hundreds of thousands of people with inner ear related disorders, a significant global unmet medical need.

www.sensorion.com

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About Cochlear Limited (ASX: COH)

Cochlear is the global leader in implantable hearing solutions. The company has a global workforce of more than 4,000 people and invests more than AUD\$180 million a year in research and development. Products include cochlear implants, bone conduction implants and acoustic implants, which healthcare professionals use to treat a range of moderate to profound types of hearing loss. Since 1981, Cochlear has provided more than 600,000 implantable devices, helping people of all ages, in more than 180 countries, to hear.

www.cochlear.com

For further information, please contact

Press Relations

Sophie Baumont
LifeSci Advisors
sophie@lifesciadvisors.com
+33 6 27 74 74 49

Investor Relations

Markus Metzger, Ph.D.
Head of Investor Relations & Corporate Communications
markus.metzger@sensorion-pharma.com
+33 6 73 61 73 97

Label: **SENSORION**
ISIN: **FR0012596468**
Mnemonic: **ALSEN**



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